DETAILED ACTION

Applicant's amendments filed January 14, 2008 have been entered.

Claims 14, 16-18, 23-25, 27, 30, and 32-62 are pending.

Claims 16-18 and 36-48 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4, received December 10, 2001.

Claims 30, and 32-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 4 received December 10, 2001.

The outstanding rejection under 35 USC 112, second paragraph is withdrawn in view of the amendments filed January 14, 2008.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 14, 23-25, 27, and 49-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dahlen et al. (WO 97/28797) in view of Katzung ("Basic & Clinical Pharmacology", 6th ed., 1995, page 312-314), and Spector et al. (J. Allergy Clin.

Immunol., 1995; 96(2):174-181) , all are references of record, and Repetabs® monograph from PDR 1994, pages 2169-2170.

Dahlen et al. teaches an asthma treating composition comprises Loratadine and Montelukast sodium (See particularly page 5, Example, whole page).

Dahlen does not expressly teach the asthma treating composition contains a adrenergic bronchodilator such as albuterol. Dahlen does not expressly teach the asthma composition containing cetirizine. Dahlen does not expressly teach the albuterol being formulated into a combination of extended release and an immediate release formulation.

Katzung teaches that albuterol is useful in treating asthma (See particularly page 314, col. 1, first paragraph).

Spector et al. teaches cetirizine is effective in treating mild-to-moderate asthma due to its significant bronchodilatory effect (See particularly the abstract).

Repetabs teaches a composition albuterol being formulated into extended release and an immediate release formulation in one (See page 2169, col. 1).

It would have been obvious to one skill in the art when the invention was made to incorporate albuterol, in a formulation that incorporate immediate release and extended release formulation, into the asthma treating composition of Dahlen et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute cetirizine for loratadine in composition of Dahlen et al.

One of ordinary skill in the art would have motivated to incorporate albuterol, in a formulation that incorporate immediate release and extended release formulation, into

the asthma treating composition of Dahlen et al. because combining agents which are known to be useful to treat asthma individually into a single composition useful for the very same purpose is prima facie obvious. See *In re Kerkhoven* 205 USPQ 1069 (CCPA 1980). One of ordinary skill in the art would have been motivated to substitute cetirizine for loratadine in composition of Dahlen et al. because both cetirizine and loratadine are both antihistamine agent and both are known to be useful in asthma treating composition. Therefore, substituting any known asthma treating antihistamine compounds, including cetirizine, for loratadine would have been reasonably expected to be useful in formulating a composition useful for treating asthma. Furthermore, incorporating any known albuterol formulations, including that of Repetab, in the asthmatic composition would be seen as obvious because simple selection among obvious alternatives is considered as being within the purview of skilled artisans, absent evidence to the contrary.

Response to Arguments

Applicant's arguments with respect to claims 14, 23-25, 27, and 49-62 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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